

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

54 orig claims

Claims 1 (Original)

A dosage form comprising a drug layer comprising 8 mg of hydromorphone, 67.8 mg of poly(ethylene oxide) of 200,000 molecular weight, 4 mg of poly(vinyl pyrrolidone), and 0.2 mg of a lubricant; a delivery layer comprising 37.8 mg of poly(ethylene oxide) possessing a 2,000,000 molecular weight, 18 mg of sodium chloride, 3 mg of hydroxypropylmethylcellulose of 9,200 molecular weight, 0.6 mg of a colorant, and 0.15 mg of a lubricant; a semipermeable wall comprising 27.2 mg of cellulose acetate of 39.8% acetyl content, and 0.275 mg of polyethylene glycol of 3,350 molecular weight; a passageway in the wall; and a controlled rate of release of 0.427 mg/hr for 17.3 hours.

Claims 2-54 (Cancelled)

Claim 55. (New)

A dosage form comprising:  
a hydromorphone deliverable at a controlled rate of 0.4 to 3.7 mg/hr over an extended time up to 24 hours.

Claim 56. (New)

The dosage form according to Claim 55, further comprising a polymeric carrier for the hydromorphone.

Claim 57. (New)

The dosage form according to Claim 56, further comprising a lubricant.

Claim 58. (New)

The dosage form according to Claim 57, further comprising a colorant.

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- Claim 59. (New) The dosage form according to Claim 58, further comprising a compression aid.
- Claim 60. (New) The dosage form according to Claim 59, further comprising a binder.
- Claim 61. (New) The dosage form according to Claim 56, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 62. (New) The dosage form according to Claim 56, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 63. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 64. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 65. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 66. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 67. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 68. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by rectal pain.

- Claim 69. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 70. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 71. (New) The dosage form according to Claim 56, wherein the hydromorphone is used for relief of pain caused by disease.
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- Claim 72. (New) A dosage form comprising:
- 10 - 100 mg of a hydromorphone deliverable at a controlled rate of 0.4 to 3.7 mg/hr over an extended time up to 24 hours.
- Claim 73. (New) The dosage form according to Claim 72, further comprising a polymeric carrier for the hydromorphone.
- Claim 74. (New) The dosage form according to Claim 73, further comprising a lubricant.
- Claim 75. (New) The dosage form according to Claim 74, further comprising a colorant.
- Claim 76. (New) The dosage form according to Claim 75, further comprising a compression aid.
- Claim 77. (New) The dosage form according to Claim 76, further comprising a binder.

- Claim 78. (New) The dosage form according to Claim 73, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 79. (New) The dosage form according to Claim 73, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 80. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 81. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 82. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 83. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 84. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 85. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 86. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 87. (New) The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by renal colic.

Claim 88. (New)                    The dosage form according to Claim 73, wherein the hydromorphone is used for relief of pain caused by disease.

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Claim 89. (New)                    A method for treating pain in a patient, the method comprising the steps of:  
providing a dosage form of a hydromorphone;  
administering the dosage form to the patient; and  
delivering the hydromorphone to the patient from the dosage form at a controlled rate of 0.4 to 3.7 mg/hr over an extended time up to 24 hours.

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Claim 90. (New)                    A method for treating pain in a patient, the method comprising the steps of:  
providing a dosage form of 10 – 100 mg of a hydromorphone;  
administering the dosage form to the patient; and  
delivering the hydromorphone to the patient from the dosage form at a controlled rate of 0.4 to 3.7 mg/hr over an extended time up to 24 hours.

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Claim 91. (New)                    A dosage form comprising:  
2 – 75 mg of a hydromorphone administerable to a patient over a 24 hour period at a controlled rate, the hydromorphone producing a plasma hydromorphone concentration from 0.01 ng to 10 ng/ml over the 24 hour period.

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Claim 92. (New)                    The dosage form according to Claim 91, further comprising a polymeric carrier for the hydromorphone.

Claim 93. (New)                    The dosage form according to Claim 92, further comprising a lubricant.

- Claim 94. (New) The dosage form according to Claim 93, further comprising a colorant.
- Claim 95. (New) The dosage form according to Claim 94, further comprising a compression aid.
- Claim 96. (New) The dosage form according to Claim 95, further comprising a binder.
- Claim 97. (New) The dosage form according to Claim 92, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 98. (New) The dosage form according to Claim 92, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 99. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 100. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 101. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 102. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 103. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by burns.

- Claim 104. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 105. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 106. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 107. (New) The dosage form according to Claim 92, wherein the hydromorphone is used for relief of pain caused by disease.
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- Claim 108. (New) A method for treating pain in a patient, the method comprising the steps of:  
providing a dosage form comprising 2 – 75 mg of a hydromorphone;  
administering the dosage form to the patient;  
delivering the hydromorphone to the patient from the dosage form at a controlled rate over a 24 hour period; and  
producing a plasma hydromorphone concentration from 0.01 ng to 10 ng/ml over the 24 hour period.
- Claim 109. (New) A method for treating pain in a patient, the method comprising the steps of:  
providing a dosage form of 1– 65 mg of a hydromorphone;  
orally administering the dosage form to the patient; and  
delivering the hydromorphone to the patient from the dosage form at a controlled rate over a period of time up to 24 hours for producing 0.01 ng to 10 ng/ml of plasma hydromorphone.

- Claim 110. (New) A method of manufacturing a therapeutic composition, the method comprising the steps of:  
providing 1 – 500 mg of a hydromorphone;  
providing at least one polymeric carrier;  
forming a composition with the hydromorphone and the at least one polymeric carrier; and  
compressing the composition at a range of ¼ to 10-ton force to yield an orally adminisiterable tablet.
- Claim 111. (New) The method according to Claim 110, further comprising providing poly(alkylene oxide) as the at least one polymeric carrier.
- Claim 112. (New) The method according to Claim 110, further comprising providing carboxymethylcellulose as the at least one polymeric carrier.
- Claim 113. (New) The method according to Claim 110, further comprising providing a lubricant to the composition.
- Claim 114. (New) The method according to Claim 113, further comprising providing a colorant to the composition.
- Claim 115. (New) The method according to Claim 114, further comprising providing a compression aid to the composition.
- Claim 116. (New) The method according to Claim 115, further comprising providing a binder to the composition.
- Claim 117. (New) A dosage form comprising:



1 – 500 mg of a hydromorphone deliverable at a controlled rate of 0.4 to 3.7 mg/hr over an extended time.

- Claim 118. (New) The dosage form according to Claim 117, further comprising a polymeric carrier for the hydromorphone.
- Claim 119. (New) The dosage form according to Claim 118, further comprising a lubricant.
- Claim 120. (New) The dosage form according to Claim 119, further comprising a colorant.
- Claim 121. (New) The dosage form according to Claim 120, further comprising a compression aid.
- Claim 122. (New) The dosage form according to Claim 121, further comprising a binder.
- Claim 123. (New) The dosage form according to Claim 118, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 124. (New) The dosage form according to Claim 118, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 125. (New) The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 126. (New) The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by cancer.

- Claim 127. (New)      The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 128. (New)      The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 129. (New)      The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 130. (New)      The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 131. (New)      The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 132. (New)      The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 133. (New)      The dosage form according to Claim 118, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 134. (New)      The dosage form according to Claim 117, wherein the extended time is up to 24 hours.
- Claim 135. (New)      The dosage form according to Claim 118, wherein the extended time is up to 24 hours.
- Claim 136. (New)      A method for treating pain in a patient, the method comprising the steps of:

providing a dosage form of 1 – 500 mg of a hydromorphone;  
administering the dosage form to the patient; and  
delivering the hydromorphone to the patient from the dosage  
form at a controlled rate of 0.4 to 3.7 mg/hr over an extended  
time.

Claim 137. (New)      The method according to Claim 136, further comprising  
delivering the hydromorphone to the patient from the dosage  
form at a controlled rate of 0.4 to 3.7 mg/hr over an extended  
time up to 24 hours.

Claim 138. (New)      A formulation comprising a poly(alkylene oxide) polymeric  
carrier and hydromorphone given once daily, the  
hydromorphone providing an average trough concentration of  
about  $0.106 \pm 0.038$  ng/mL per mg hydromorphone at steady  
state.

Claim 139. (New)      The formulation according to Claim 138, further comprising a  
lubricant.

Claim 140. (New)      The formulation according to Claim 139, further comprising a  
colorant.

Claim 141. (New)      The formulation according to Claim 140, further comprising a  
compression aid.

Claim 142. (New)      The formulation according to Claim 141, further comprising a  
binder.

Claim 143. (New)      The formulation according to Claim 138, wherein the  
hydromorphone is used for relief of pain caused by surgery.

- Claim 144. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 145. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 146. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 147. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 148. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 149. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 150. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 151. (New)            The formulation according to Claim 138, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 152. (New)            A formulation comprising a carboxymethylcellulose polymeric carrier and hydromorphone given once daily, the hydromorphone providing an average trough concentration of

about  $0.106 \pm 0.038$  ng/mL per mg hydromorphone at steady state.

- Claim 153. (New) The formulation according to Claim 152, further comprising a lubricant.
- Claim 154. (New) The formulation according to Claim 153, further comprising a colorant.
- Claim 155. (New) The formulation according to Claim 154, further comprising a compression aid.
- Claim 156. (New) The formulation according to Claim 155, further comprising a binder.
- Claim 157. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 158. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 159. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 160. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 161. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by burns.

- Claim 162. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 163. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 164. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 165. (New) The formulation according to Claim 152, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 166. (New) A formulation comprising a poly(alkylene oxide) polymeric carrier and hydromorphone given once daily, the hydromorphone providing an average trough concentration ranging from about 0.068 to about 0.144 ng/mL per mg hydromorphone at steady state.
- Claim 167. (New) The formulation according to Claim 166, further comprising a lubricant.
- Claim 168. (New) The formulation according to Claim 167, further comprising a colorant.
- Claim 169. (New) The formulation according to Claim 168, further comprising a compression aid.
- Claim 170. (New) The formulation according to Claim 169, further comprising a binder.

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- Claim 171. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 172. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 173. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 174. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 175. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 176. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 177. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 178. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 179. (New)      The formulation according to Claim 166, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 180. (New)      A formulation comprising a carboxymethylcellulose polymeric carrier and hydromorphone given once daily, the

hydromorphone providing an average trough concentration ranging from about 0.068 to about 0.144 ng/mL per mg hydromorphone at steady state.

- Claim 181. (New) The formulation according to Claim 180, further comprising a lubricant.
- Claim 182. (New) The formulation according to Claim 181, further comprising a colorant.
- Claim 183. (New) The formulation according to Claim 182, further comprising a compression aid.
- Claim 184. (New) The formulation according to Claim 183, further comprising a binder.
- Claim 185. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 186. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 187. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 188. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 189. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by burns.



- Claim 190. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 191. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 192. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 193. (New) The formulation according to Claim 180, wherein the hydromorphone is used for relief of pain caused by disease.
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- Claim 194. (New) A formulation comprising hydromorphone given once daily that provides a maximum concentration around 0.16 ng/mL per mg hydromorphone at steady state.
- Claim 195. (New) The formulation according to Claim 194, further comprising a polymeric carrier for the hydromorphone.
- Claim 196. (New) The formulation according to Claim 195, further comprising a lubricant.
- Claim 197. (New) The formulation according to Claim 196, further comprising a colorant.
- Claim 198. (New) The formulation according to Claim 197, further comprising a compression aid.

- Claim 199. (New)            The formulation according to Claim 198, further comprising a binder.
- Claim 200. (New)            The formulation according to Claim 195, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 201. (New)            The formulation according to Claim 195, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 202. (New)            The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 203. (New)            The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 204. (New)            The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 205. (New)            The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 206. (New)            The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 207. (New)            The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 208. (New)            The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by biliary colic.

- Claim 209. (New) The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 210. (New) The formulation according to Claim 194, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 211. (New) A formulation comprising hydromorphone given once daily that provides an average trough concentration ranging from about 0.068 to about 0.144 ng/mL per-mg hydromorphone and a maximum concentration around 0.16 ng/mL per mg hydromorphone at steady state.
- Claim 212. (New) The formulation according to Claim 211, further comprising a polymeric carrier for the hydromorphone.
- Claim 213. (New) The formulation according to Claim 212, further comprising a lubricant.
- Claim 214. (New) The formulation according to Claim 213, further comprising a colorant.
- Claim 215. (New) The formulation according to Claim 214, further comprising a compression aid.
- Claim 216. (New) The formulation according to Claim 215, further comprising a binder.
- Claim 217. (New) The formulation according to Claim 212, wherein the polymeric carrier comprises poly(alkylene oxide).

- Claim 218. (New) The formulation according to Claim 212, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 219. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 220. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 221. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 222. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 223. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 224. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 225. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 226. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 227. (New) The formulation according to Claim 211, wherein the hydromorphone is used for relief of pain caused by disease.

- Claim 228. (New) A formulation comprising hydromorphone given once daily that provides an average AUC of about  $2.8 \pm 0.25$  ng/mL/hr per mg hydromorphone, and an average trough concentration of about  $0.106 \pm 0.038$  ng/mL per mg hydromorphone at steady state.
- Claim 229. (New) The formulation according to Claim 228, further comprising a polymeric carrier for the hydromorphone.
- Claim 230. (New) The formulation according to Claim 229, further comprising a lubricant.
- Claim 231. (New) The formulation according to Claim 230, further comprising a colorant.
- Claim 232. (New) The formulation according to Claim 231, further comprising a compression aid.
- Claim 233. (New) The formulation according to Claim 232, further comprising a binder.
- Claim 234. (New) The formulation according to Claim 229, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 235. (New) The formulation according to Claim 229, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 236. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by surgery.

- Claim 237. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 238. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 239. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 240. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 241. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 242. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 243. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 244. (New) The formulation according to Claim 228, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 245. (New) A formulation comprising hydromorphone given once daily that provides an average AUC ranging from about 2.55 to about 3.05 ng/mL/hr per mg hydromorphone, and an average trough concentration ranging from about 0.068 to about 0.144 ng/mL per mg hydromorphone at steady state.

- Claim 246. (New) The formulation according to Claim 245, further comprising a polymeric carrier for the hydromorphone.
- Claim 247. (New) The formulation according to Claim 246, further comprising a lubricant.
- Claim 248. (New) The formulation according to Claim 247, further comprising a colorant.
- Claim 249. (New) The formulation according to Claim 248, further comprising a compression aid.
- Claim 250. (New) The formulation according to Claim 249, further comprising a binder.
- Claim 251. (New) The formulation according to Claim 246, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 252. (New) The formulation according to Claim 246, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 253. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 254. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 255. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by trauma.

- Claim 256. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 257. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 258. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 259. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 260. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 261. (New) The formulation according to Claim 245, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 262. (New) A formulation comprising hydromorphone given once daily that provides an average AUC of about  $2.8 \pm 0.25$  ng/mL/hr per mg hydromorphone, and a maximum concentration around 0.16 ng/mL per mg hydromorphone at steady state.
- Claim 263. (New) The formulation according to Claim 262, further comprising a polymeric carrier for the hydromorphone.
- Claim 264. (New) The formulation according to Claim 263, further comprising a lubricant.



- Claim 265. (New) The formulation according to Claim 264, further comprising a colorant.
- Claim 266. (New) The formulation according to Claim 265, further comprising a compression aid.
- Claim 267. (New) The formulation according to Claim 266, further comprising a binder.
- Claim 268. (New) The formulation according to Claim 263, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 269. (New) The formulation according to Claim 263, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 270. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 271. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 272. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 273. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 274. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by burns.

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- Claim 275. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 276. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 277. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 278. (New) The formulation according to Claim 262, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 279. (New) A formulation comprising hydromorphone given once daily that provides an average AUC ranging from about 2.55 to about 3.05 ng/mL/hr per mg hydromorphone, and a maximum concentration around 0.16 ng/mL per mg hydromorphone at steady state.
- Claim 280. (New) The formulation according to Claim 279, further comprising a polymeric carrier for the hydromorphone.
- Claim 281. (New) The formulation according to Claim 280, further comprising a lubricant.
- Claim 282. (New) The formulation according to Claim 281, further comprising a colorant.
- Claim 283. (New) The formulation according to Claim 282, further comprising a compression aid.

- Claim 284. (New) The formulation according to Claim 283, further comprising a binder.
- Claim 285. (New) The formulation according to Claim 280, wherein the polymeric carrier comprises poly(alkylene oxide).
- Claim 286. (New) The formulation according to Claim 280, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 287. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 288. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 289. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 290. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 291. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 292. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 293. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by biliary colic.

- Claim 294. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 295. (New) The formulation according to Claim 279, wherein the hydromorphone is used for relief of pain caused by disease.
- Claim 296. (New) A formulation comprising hydromorphone given once daily that provides an average AUC ranging from about 2.55 to about 3.05 ng/mL/hr per mg hydromorphone, and an average trough concentration ranging from about 0.068 to about 0.144 ng/mL per mg hydromorphone and a maximum concentration around 0.16 ng/mL per mg hydromorphone at steady state.
- Claim 297. (New) The formulation according to Claim 296, further comprising a polymeric carrier for the hydromorphone.
- Claim 298. (New) The formulation according to Claim 297, further comprising a lubricant.
- Claim 299. (New) The formulation according to Claim 298, further comprising a colorant.
- Claim 300. (New) The formulation according to Claim 299, further comprising a compression aid.
- Claim 301. (New) The formulation according to Claim 300, further comprising a binder.
- Claim 302. (New) The formulation according to Claim 297, wherein the polymeric carrier comprises poly(alkylene oxide).

- Claim 303. (New)            The formulation according to Claim 297, wherein the polymeric carrier comprises carboxymethylcellulose.
- Claim 304. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by surgery.
- Claim 305. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by cancer.
- Claim 306. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by trauma.
- Claim 307. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by myocardial infarction.
- Claim 308. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by burns.
- Claim 309. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by rectal pain.
- Claim 310. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by biliary colic.
- Claim 311. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by renal colic.
- Claim 312. (New)            The formulation according to Claim 296, wherein the hydromorphone is used for relief of pain caused by disease.